UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

In re Novartis and Par Antitrust Litigation	**1:18-cv-04361-AKH**
This Document Relates To: **All Actions**	

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION TO COMPEL THIRD PARTY MYLAN TO PRODUCE DOCUMENTS RESPONSIVE TO SUBPOENA

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I. INTRODUCTION

Direct Purchaser Plaintiffs and End-Payor Plaintiffs (collectively, "Plaintiffs") allege, among other things, that Novartis made a reverse payment to Par in exchange for an agreement to delay Par's launch of generic Exforge until September 30, 2014.[1] Because Par was eligible for an exclusive marketing period as the first to file generic applicant, Par's agreement not to launch its generic Exforge created a bottleneck that prevented subsequent generic applicants, like Mylan, from obtaining FDA approval to sell generic Exforge until the expiration of Par's 180-day exclusivity period.[2] Thus, Plaintiffs have alleged that Par's and Novartis's agreement to delay the launch of generic Exforge until September 30, 2014 also delayed other generic companies, like Mylan, from obtaining approval for and launching generic Exforge until March 30, 2015 (181 days after Par's generic Exforge launch). The Defendants' agreement not only delayed entry of Par's generic Exforge, it also delayed access to an even lower priced generic Exforge (since generic Exforge prices would have been lower with more generics on the market), causing additional economic harm to Plaintiffs.[3]

Consequently, whether Mylan would have been, ready, willing, and able to market generic Exforge earlier than March 2015, when Par's 180-day exclusivity period ended, is an issue in this case. In other delayed-generic antitrust cases, courts have repeatedly recognized that evidence of when other generic filers would have been ready, willing and able to market their generic products was relevant to issues of, without limitation, causation and damages. *See, e.g., In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d 152, 169-72 (S.D.N.Y. 2018) ("*Namenda I*");

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[1] Dkt. No. 47, Am. Complaint, ¶ 6. Cites to the "Am. Complaint" are to the DPPs' complaint. EPPs' complaint, at Dkt. No. 25, alleges the same conduct.

[2] *Id*. at ¶¶ 11, 132-137.

[3] *Id*. at ¶¶ 11, 135-137.

In re Neurontin Antitrust Litig., No. 02-1390 FSH, 2013 WL 4042460, at *10 (D.N.J. Aug. 8, 2013) (defendant unsuccessfully argued at summary judgment that "Plaintiffs cannot establish that any alleged antitrust misconduct caused their injury because" generic manufacturer "did not obtain FDA approval" in time). In order to obtain this relevant evidence from Mylan, Plaintiffs served a subpoena on Mylan seeking, *inter alia*, manufacturing, business, and regulatory documents, showing Mylan's generic Exforge planning, capacity, and launch preparation actions.

After several rounds of negotiations, during which Plaintiffs agreed to significantly narrow their requests, Mylan has agreed only to produce certain discrete, limited categories of documents—and stands on its objections of relevance and burden with respect to the remaining categories of documents Plaintiffs seek. Additionally, Mylan has refused to search any custodian's files for responsive documents and has refused to produce the majority of documents relating to Mylan's ability and willingness to launch its generic Exforge product earlier than it did. In addition, unlike other third-party generic manufacturers who have received similar subpoenas in this case, and despite agreeing in principle to produce certain categories of documents, Mylan is refusing to produce *any* documents responsive to *any* requests until such time that Plaintiffs and Mylan may agree to the entire scope of production (or, presumably, until ordered to produce responsive documents by the Court).[4] Mylan has refused to produce, for example, its generic Exforge sales data, because Plaintiffs and Mylan have not yet reached agreement on the scope of Mylan's production of other documents, despite the lack of dispute as to the relevance of and lack of burden to producing this sales data.

[4] Ex. 6 at 4. Multiple other generic pharmaceutical manufacturers with whom Plaintiffs are still negotiating regarding certain subpoena requests have already produced documents and sales data responsive to other requests included in the subpoenas to those generics.

Accordingly, Plaintiffs respectfully request that the Court intervene and order Mylan to produce documents responsive to Plaintiffs' subpoena Request Nos. 3 and 4 (to the extent Mylan has not already agreed to produce documents responsive to these requests), and No. 5, which are more fully described below. Plaintiffs also respectfully request that the Court order Mylan to promptly produce all documents it has already indicated it is willing and able to produce, but has refused to thus far given the lack of agreement on *other* requests, namely, agreed-upon categories of documents responsive to Request Nos. 1, 2, 3 and 4 (in part), 5, 7, 8, 9, and 15.

II. BACKGROUND

On December 6, 2018, Plaintiffs served a Rule 45 subpoena on Mylan, to be answered by January 4, 2019. *See* Ex. 1.[5] After asking for and receiving an extension from Plaintiffs, Mylan served its objections and responses to the subpoena on January 10, 2019. *See* Ex. 2.[6] Thereafter, Plaintiffs and Mylan communicated multiple times through letters and telephone conferences in an attempt to resolve Mylan's objections, including the following communications:

- February 4, 2019 (telephone conference);[7]
- February 15, 2019 (telephone conference);
- February 25, 2019 (Plaintiffs' letter to Mylan (Ex. 3));
- March 15, 2019 (Mylan's letter to Plaintiffs (Ex. 4));
- April 1, 2019 (Plaintiffs' letter to Mylan (Ex. 5));
- April 8, 2019 (telephone conference); and
- April 15, 2019 (Plaintiffs' letter to Mylan (Ex. 6)).

[5] Exhibits referenced herein are attached to the Declaration of Dan Litvin, filed contemporaneously herewith.

[6] These objections and responses were received on January 10, 2019, despite being misdated as January 10, 2018.

[7] Meet and confer telephone conferences were attended by Dan Chiorean, Robin van der Meulen, and Deborah Elman on behalf of Plaintiffs and Brendan J. Coffman on behalf of Mylan.

Plaintiffs and Mylan compromised and reached agreements regarding the scope of Mylan's production in response to several of the subpoena's requests,[8] but Mylan has refused to produce *any* documents until agreement is reached on the full scope of the subpoena.[9] Specifically, Mylan has agreed that once the entire scope of production is resolved, it is willing to produce documents responsive to the following requests, as narrowed by Plaintiffs during our multiple meet and confers:

Request No.	**Topic**
1	Paragraph IV Certification Letters sent to Novartis;
2	Mylan's detailed forecasts, including without limitation those that account for the launch of a Novartis Authorized Generic, from the date Mylan's Abbreviated New Drug Application ("ANDA") was filed through June 1, 2015;
3	Mylan's regulatory correspondence file (*i.e.*, only external communications with FDA) for its generic Exforge ANDA No. 90-483, but not the remainder of the documents sought by Request No. 3;
4(i) & (ii)	Mylan's forecasts, but not the remainder of the documents sought by Request 4(i) & (ii);
4(vii) & 5	Mylan's scale-up documents, but not the remainder of the documents sought by Request Nos. 4(vii) and 5;
7	Mylan's sales data for generic Exforge showing all sales, returns, chargebacks, and price adjustments to direct purchasers for the time period March 30, 2015 through December 31, 2018;[10]
8 & 9	Mylan's sales data to End Payors for Mylan's generic Exforge product (if Mylan has such data); and

[8] *See generally* Ex. 6.

[9] Ex. 6 at 4.

[10] Plaintiffs accepted this compromise with the caveat that they will need to verify, after receiving Mylan's production, that the produced chargeback data includes the requested contract/indirect customer names and addresses. *See id.* at 3.

15	Non-privileged Mylan communications with other third parties regarding pending or threatened litigation by Novartis or another generic competitor regarding Exforge.

Plaintiffs agreed to forego documents pursuant to Request Nos. 12-14 and 16-21. Additionally, Mylan represented that it is still investigating whether it possesses documents responsive to Request Nos. 8-10. Mylan represented it does not possess any documents responsive to Request No. 11.

However, despite extensive meet and confers, Mylan refuses to produce large categories of documents responsive to Requests concerning Mylan's readiness, willingness, and ability to come to market earlier with its generic Exforge (Request Nos. 3-5). Specifically, Mylan has refused to produce:

Request No.	**Topic**
3	Mylan's internal correspondence showing its efforts to obtain approval for its ANDA and other regulatory work during the time period beginning with the date Mylan filed its ANDA and ending on June 1, 2015;[11]
4(i)	Mylan's generic Exforge launch timelines, new product launch meeting minutes, and projections for the time period starting on the date Mylan filed its ANDA and ending on May 1, 2015;[12]
4(iii)	Mylan's generic Exforge launch updates, action items from new product launch meetings, and launch team meeting minutes for the time period starting on the date Mylan filed its ANDA and ending on May 1, 2015;[13]
4(iv)	Mylan's generic Exforge "at-risk" launch analysis and discussions for the time period starting on the date Mylan filed its ANDA and ending on May 1, 2015;[14]

[11] Ex. 5 at 2-3, 4; Ex. 6 at 2.

[12] Ex. 5 at 2, 4-5; Ex. 6 at 2. As noted above, however, Mylan has agreed to produce Mylan "forecasts," but not the remainder of the documents sought by Request No. 4(i). *See supra* at 5.

[13] Ex. 5 at 2, 4-5; Ex. 6 at 2.

[14] Ex. 5 at 2, 4-5; Ex. 6 at 2.

4(v)	Mylan's manufacturing forecasts for the time period starting on the date Mylan filed its ANDA and ending on May 1, 2015;[15]
4(vi)	Documents concerning sourcing of active and inactive generic Exforge ingredients (including communications with any suppliers) for the time period starting on the date Mylan filed its ANDA and ending on May 1, 2015;[16]
4(vii)	Documents concerning Exforge exhibit batches, scale up efforts, validation batches, building and maintenance of commercial quantities and/or manufacture, sale, transfer, or destruction of the same for the time period starting on the date Mylan filed its ANDA and ending on May 1, 2015;[17] and
5	Documents concerning whether Mylan could or would have launched generic Exforge before September 30, 2014. Plaintiffs seek documents for the time period starting on the date Mylan filed its ANDA and ending on May 1, 2015.[18]

Accordingly, Plaintiffs respectfully request that the Court order Mylan to produce these categories of documents responsive to Plaintiffs' subpoena Request Nos. 3-5, and order Mylan to immediately produce the agreed-upon categories of documents responsive to Request Nos. 1, 2, 3, 4, 5, 7, 8, 9, and 15, as set forth above.

III. LEGAL STANDARD

Motions to compel and motions to quash a subpoena are both "entrusted to the sound discretion of the district court." *In re Fitch, Inc.*, 330 F.3d 104, 108 (2d Cir. 2003) (citing *United States v. Sanders*, 211 F.3d 711, 720 (2d Cir. 2000)); *accord In re World Trade Ctr. Disaster Site*

[15] Ex. 5 at 2, 4-5; Ex. 6 at 2.

[16] Ex. 5 at 2, 4-5; Ex. 6 at 2.

[17] Ex. 5 at 2, 4-5; Ex. 6 at 2. As noted above, however, Mylan has agreed to produce Mylan "scale-up documents," but not the remainder of the documents sought by Request Nos. 4(vii) and 5. *See supra* at 5.

[18] Ex. 5 at 2, 6; Ex. 6 at 2; Ex. 1 at 9-10.

Litig., No. 05-cv-9141, 2009 WL 4722250, at *2 (S.D.N.Y. Dec. 9, 2009) (Hellerstein, J.) (citing *In re Fitch*, 330 F.3d at 108).

"The relevance standards set out in Federal Rule of Civil Procedure 26(b)(1) apply to discovery sought from non-parties," which provides that "Parties may obtain discovery regarding any non privileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit." *Mackey v. IDT Energy, Inc.*, No. 19 MISC. 29 (PAE), 2019 WL 2004280, at *3 (S.D.N.Y. May 7, 2019) (citing *Citizens Union of City of N.Y. v. Attorney General of N.Y.*, 269 F. Supp. 3d 124, 139 (S.D.N.Y. 2017) and Fed. R. Civ. P. 26(b)(1)). "'The party seeking discovery bears the initial burden of proving the discovery is relevant.'" *Mackey*, 2019 WL 2004280, at *3 (quoting *Citizens Union of City of N.Y.*, 269 F. Supp. 3d at 139). "If the party issuing the subpoena establishes the relevance of the materials sought, the burden then shifts to the movant to demonstrate an undue burden." *Mackey*, 2019 WL 2004280, at *3 (citing *Griffith v. United States*, No. M8-85 (JFK), 2007 WL 1222586, at *2 (S.D.N.Y. Apr. 25, 2007)). "Whether a subpoena imposes an undue burden depends upon such factors as relevance, the need of the party for the documents, the breadth of the document, the time period covered by it, the particularity with which the documents are described and the burden imposed." *Mackey*, 2019 WL 2004280, at *3 (quoting *Night Hawk Ltd. v. Briarpatch Ltd.*, No. 03 Civ. 1382 (RWS), 2003 WL 23018833, at *8 (S.D.N.Y. Dec. 23, 2003) (internal quotations omitted)); *see also In re Biovail Corp. Sec. Litig.*, 247 F.R.D. 72, 74 (S.D.N.Y. 2007) ("where, as here, [information] is sought from third parties, the Court must weigh the probative value of the information against the

burden of production on said non-parties."). The trial court has broad discretion to determine whether a subpoena imposes an undue burden. *Mackey*, 2019 WL 2004280, at *3 (citing *Jones v. Hirschfeld*, 219 F.R.D. 71, 74 (S.D.N.Y. 2003)).

IV. ARGUMENT

A. The Discovery Sought Is Relevant in Reverse Payment Cases

Evidence that, absent Defendants' conduct, Mylan would have been ready, willing, and able to market generic Exforge earlier than March 2015 (when Mylan launched immediately after Par's 180-day exclusivity ended) is relevant to Plaintiffs' proof of causation and damages, as courts have recognized in similar delayed-generic-drug antitrust cases. *See, e.g.*, *Namenda I*, 331 F. Supp. 3d at 169-72; *Neurontin*, 2013 WL 4042460 at *10 (rejecting defendant's argument at summary judgment that "Plaintiffs cannot establish that any alleged antitrust misconduct caused their injury because" generic manufacturer "did not obtain FDA approval" in time); *In re Namenda Direct Purchaser Antitrust Litig.*, No. 15-civ-7488 (CM) (JCF), 2017 WL 3822883, at *5 (S.D.N.Y. Aug. 30, 2017) ("*Namenda II*") (documents sought are "integral to a meaningful understanding of the company's efforts to launch the product").

Mylan argues that Plaintiffs have "failed to explain the relevance of many of their requests,"[19] and that Plaintiffs have not shown a "legitimate need" for the documents Mylan has refused to produce.[20] However, as Plaintiffs have explained to Mylan, because Plaintiffs allege that later filing generic manufacturers, such as Mylan, would have been ready, willing, and able to launch earlier than March 2015 absent the Novartis-Par agreement, Mylan's documents are relevant to show whether it had the capability, equipment, manpower, facilities, ingredients,

[19] Ex. 4 at 1.

[20] *Id.* at 3.

packaging, planning, regulatory approval (or ability to obtain such approval), and other capabilities to effectuate an earlier launch.[21] Moreover, Plaintiffs cannot obtain this information about Mylan from any entity other than Mylan.

Notwithstanding its objection, Mylan cannot seriously dispute the relevance of its ability and willingness to market its generic product earlier. Mylan itself has been a defendant or plaintiff in a number of similar pharmaceutical antitrust cases, and has repeatedly argued that information about a company's ability and willingness to launch is relevant. For instance, Mylan's proposed jury instructions in a recent case argued the importance of proving that Mylan and other generic companies "could and would have lawfully launched a generic [] product in the United States," and that the challenged agreement "caused a delay in the lawful launch."[22]

Disputed Request Nos. 3-5 all go to Mylan's readiness, ability, and/or willingness to launch its generic Exforge product earlier, or the timing of when Mylan would have launched generic Exforge absent Defendants' allegedly unlawful conduct. In sum, the information sought by the Requests in dispute is relevant to this case (as Mylan itself has argued in other cases), needed by Plaintiffs, and only obtainable from Mylan.

B. The Requests Are Not Unduly Burdensome to Mylan

Plaintiffs' subpoena was narrowly tailored to seek relevant documents, which Plaintiffs' counsel identified based on our extensive experience litigating similar pharmaceutical antitrust cases. Additionally, in an effort to mitigate any burden on a third party like Mylan, Plaintiffs have

[21] Ex. 5 at 3, 5.

[22] Ex. 7, Defendants' Proposed Preliminary Jury Instructions, Dkt. No. 991-4, *King Drug Company of Florence, Inc. vs. Cephalon, Inc., et al.*, Case 2:06-cv-01797-MSG (E.D. Pa., Jan. 13, 2016), at 27 ("In order to prove that a patent litigation settlement caused that Plaintiffs' alleged injuries, Plaintiffs must first prove that the settling Generic Defendant could and would have lawfully launched a generic Provigil product in the United States in 2006 if that settlement had not been entered into, as the Plaintiffs have alleged they would."); *id.* at 23.

agreed to forgo several of their original Requests, as well as to narrow nearly all the other Requests—both in time period and subject matter. *See generally* Exs. 5, 6 (summarizing the agreements with Mylan thus far, including which Requests Plaintiffs agreed to drop, as well as the extent to which Plaintiffs agreed to further narrow other requests). Compliance with the remaining, narrowed Requests in dispute would not unduly burden Mylan.

Notwithstanding Plaintiffs' compromises, Mylan has flatly refused to conduct *any* custodial searches or run search terms in order to identify responsive documents, alleging that doing so would be "unduly burdensome, unnecessary in light of what we have offered to produce, and not proportionate to the needs of plaintiffs."[23] Mylan has claimed undue burden despite not providing any substantiation of the claimed burden,[24] and despite acknowledging in similar cases that its internal custodians and departments would have responsive information.[25]

But a custodial review of documents is a standard feature of modern discovery.[26] What Mylan "describes as an undue burden is merely the typical process for a corporation responding to document requests." *Kenyon v. Simon & Schuster, Inc.*, No. 16 MISC. 327 (P1), 2016 WL

[23] Ex. 4, at 2.

[24] Although Mylan has provided some very vague, minimal information in this case regarding potential costs of production, Mylan has not indicated the number of documents at issue nor the number of custodians with potentially relevant information. *See, e.g.*, *id.* at 6 (Mylan estimating that its "[c]ompliance with plaintiffs' subpoena will require vastly more resources than usual, potentially reaching six-digit figures. While Mylan's costs can change depending on the scope of any agreement we may reach, Mylan will be willing to detail the costs of compliance when we reach that step.").

[25] *See, e.g.*, *infra*, at 11-12 (discussing the *Doryx* case).

[26] The Court's September 26, 2018, Order regarding production of documents also contemplates that third parties would identify custodians and produce documents therefrom. *See, e.g.*, Dkt. No. 25, at 17, ¶ 5.2 ("After the Producing Party serves its Responses and Objections to Requests for Production, the Producing Party shall identify its own proposed individual custodians (including their title) within 14 days."); *see also id.* at 3, ¶ 1.10 (defining "Producing Party" as "any Party or third party that produces hard copy or ESI Documents in this Action.").

5930265, at *5 (S.D.N.Y. Oct. 11, 2016), (citing *The Sedona Conference, The Sedona Conference Best Practices Commentary on the Use of Search & Information Retrieval Methods in E-Discovery*, 2014 Sedona Conf. J. 217, 244 (2014)). It is common, in response to a Rule 45 subpoena, for parties to agree to run custodial searches on a "reasonable number of custodians and a reasonable list of keywords to search." *Id.* at *7.

For example, when Mylan itself was a plaintiff in a pharmaceutical antitrust case (the "*Doryx* case"), it proposed a "discovery approach ... aimed to strike an appropriate balance on the sliding scale of relevancy versus burden."[27] For the drug at issue in the *Doryx* case, Mylan proposed producing a much larger collection of documents than Plaintiffs have requested from Mylan in this case, which involves similar issues, scale, and damages. *See, e.g., id.* at 3. Notably, the much broader set of documents offered up by Mylan in the *Doryx* case encompass several subsets of documents that Mylan claims are too burdensome to produce in this case, such as "[a]ll responsive files from Regulatory department and senior employees regarding communications with FDA" and "[a]ll responsive files from Commercial Operations and Launch Management (aka Project Management) departments and senior employees regarding logistics and planning for launching products."[28] Also, of note, Mylan agreed that it was "reasonable" in that case to search "nineteen individual custodians and nine departmental custodians" regarding the drug at issue.[29] In this case, recognizing that Mylan is a third party, Plaintiffs are only asking Mylan to produce a smaller set of documents, from a smaller set of custodians.[30] However, like the same documents

[27] Ex. 8, Dkt. No. 107, *Mylan Pharms. v. Warner Chilcott, et al.*, Case 2:12-cv-03824-PD (E.D. Pa., Nov. 12, 2012), at 3.

[28] *Id.*

[29] *Id.* at 2.

[30] *See, e.g.*, Ex. 5, at 4 ("[T]his request is proportional, and does not seek every document or every email from every Mylan custodian discussing Mylan's ANDA. Rather, a targeted search of one

in the *Doryx* case, these documents are clearly relevant, not unduly burdensome, and well within Mylan's ability to produce.

Moreover, Mylan's own pleadings in other similar, contemporaneous cases make clear that it is not unduly burdensome to seek custodial information from third parties. Indeed, at the same time Mylan was objecting to searching custodial documents as unduly burdensome for this case, Mylan itself was seeking custodial searches from a third party in another set of coordinated pharmaceutical antitrust cases. On December 21, 2018, Mylan filed an ultimately successful motion to compel, seeking "an order requiring non-party The Segal Group, Inc. ("Segal") to identify custodians likely to have information relevant to Mylan's subpoena and to search for and produce email communications from those custodians."[31] Mylan contended the information sought by the subpoena was "clearly relevant to, among other issues, whether [Plaintiff] suffered any injury due to [Defendants'] actions" and "what a reasonable damages model may look like."[32] In seeking that discovery, Mylan claimed that "[t]here is no valid basis for Segal's refusal to identify and search proper ESI custodians,"[33] and that "[i]n the modern era, electronic communications are ubiquitous, and it is routine for subpoenas to seek such discovery of ESI. . . . Segal's refusal to produce e-mails from custodians likely to have relevant documents without

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or two custodians during the narrow time period beginning with the date Mylan filed its ANDA and ending on 6/1/2015 would be sufficient for Plaintiffs' needs."); *id.* at 5 ("For subparts (iv) and (vi) [of Request No. 4], Plaintiffs believe that targeted, efficient searches of two or three custodians limited to the time period Plaintiffs seek can be used to obtain the documents we seek.").

[31] *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Practices & Antitrust Litig.*, No. 17-MD-2785-DDC-TJJ, 2019 WL 1004145, at *1 (D. Kan. Feb. 28, 2019).

[32] *Id.* at *2, n.12; Ex. 9 at 6 (same). Segal was not a potentially excluded or delayed competitor, but rather a third party through whom one of the class representatives communicated, negotiated, and contracted with pharmacy benefit managers. *See In re EpiPen*, 2019 WL 1004145, at *2.

[33] Ex. 9 at 2.

providing an evidentiary basis of burden is unreasonable."[34] Mylan also argued that "Segal has taken the position that any email search at all is unreasonable, which is contrary to law."[35] Just like the third-party discovery Mylan itself successfully compelled in the *EpiPen* case, Mylan should be required to conduct reasonable custodial searches for the relevant information sought by Plaintiffs in this case.

Mylan has also not substantiated its burden claim, which requires the Court to weigh the burden to the subpoenaed party against the value of the information to the serving party.[36] This analysis depends upon factors such as relevance, the need of the party for the documents, the breadth of the document request, the time period covered by it, the particularity with which the documents are described and the burden imposed. *Namenda II*, 2017 WL 3822883, at *6 (rejecting a third party subpoena target's unsubstantiated burden claim as "anemic"); *AmTrust N. Am., Inc. v. Preferred Contrs. Ins. Co. Risk Retention Grp., LLC*, No. 16-mc-0340 (CM), 2016 U.S. Dist. LEXIS 145705, at *12 (S.D.N.Y. Oct. 18, 2016) (rejecting burden claim), (citing *Copantitla v. Fiskardo Estiatorio, Inc.*, No. 09 CIV. 1608, 2010 U.S. Dist. LEXIS 33430, at *32 (S.D.N.Y. Apr. 5, 2010)). Despite Mylan's refusals to produce the documents Plaintiffs seek and its contention that these requests are "excessively burdensome and costly," Mylan has not substantiated its

[34] *Id.* at 8-9.

[35] Ex. 10 at 7 n.8.

[36] In Mylan's motion to compel in the *EpiPen* case, Mylan criticized third party Segal for similarly failing to substantiate Segal's claimed burden of the compelled production, and for refusing to discuss certain custodial searches. *See, e.g.*, Ex. 9 at 10 ("Segal has not met its obligation to show that the clear relevance of the information sought is outweighed by any burden at all. Nowhere in Segal's Objections and Responses does Segal articulate why undue burden would result from these searches. Segal therefore has not provided Mylan with any indication of the number of documents at issue, the potential number of custodians with relevant information, or any estimated costs connected to compliance with Mylan's Subpoena. Nor could it have done so, given that Segal has refused even to discuss to the custodians that Mylan is seeking.").

objections by "detailing the volume of documents at issue or the number of personnel hours that would be necessary to produce the [requested] documents." *In re Namenda Direct Purchaser Antitrust Litig.*, 15 Civ. 7488, 2017 WL 4700367, at *6 (S.D.N.Y. Oct. 19, 2017) ("*Namenda III*").

In response to a portion of Request No. 3, Mylan has agreed to produce only the external regulatory correspondence for its application to the FDA to sell generic Exforge (ANDA No. 90-483), but it has refused to search for and produce related internal Mylan correspondence and documents from custodial or other document searches (including, *e.g.*, email correspondence and meeting minutes) sufficient to show efforts to obtain approval for this application. Mylan's offer is insufficient. The number of custodians at issue here is limited, and within a sophisticated company like Mylan, these types of documents are typically generated and maintained by a defined regulatory department. Moreover, because Mylan has identified relevant custodians and departments for similar information in similar litigation,[37] any burden on Mylan to do so in this case is mitigated. Mylan has not provided meaningful information regarding the burden of fully complying with this request.

Likewise, responsive to a portion of Request Nos. 4 and 5, Mylan has agreed to produce certain forecasts and launch-preparation-related documents (what Mylan calls "scale-up documents"), but has refused to search for the bulk of documents responsive to these requests, including:

- Generic Exforge launch timelines, new product launch meeting minutes, launch updates, action items from new product launch meetings, launch team meeting minutes;
- Generic Exforge "at-risk" launch analyses and discussions;
- Sourcing of generic Exforge active and inactive ingredients used in

[37] *See, e.g.*, *supra* at 11-12 (discussing Mylan's production of a broader set of regulatory documents in the *Doryx* case); *see also* Ex. 8 at 3.

manufacturing its generic Exforge, related communications with suppliers of those ingredients (including orders placed);

- Documents regarding manufacturing sites, facilities, equipment, and other resources used in the development, scale-up, validation, commercial manufacturing, and launch of Mylan's generic Exforge;

- Documents concerning CGMP,[38] facility inspections, manufacturing, quality control, or quality assurance regarding any manufacturing sites used in the launch its generic Exforge;

- Documents relating to actual or theoretical manufacturing capacity and the limiters on that capacity to produce Mylan's generic Exforge;

- Documents sufficient to show amount of inventory of generic Exforge that Mylan had on hand at the time of anticipated launch of its generic Exforge;

- Documents sufficient to show batch sizes, manufacturing process, throughput times per batch, and manufacturing rates for Mylan's generic Exforge; and

- Any other documents concerning why Mylan could not or would not launch generic Exforge prior to September 30, 2014.

Mylan has not provided meaningful information regarding the burden of complying with these Requests, and has refused to even consider conducting custodial or search term searches. Moreover, the categories of documents Mylan refuses to produce are precisely the kind of documents the *Namenda* court said would be relevant to whether a generic could have entered the market earlier. Such evidence could bear on: (i) issues regarding the supply of excipients (inactive ingredients); (ii) whether there would have been any equipment failures or manufacturing issues earlier in the but-for world that did not exist when Mylan actually launched its generic Exforge in

[38] Current Good Manufacturing Practices are "[t]he main regulatory standard for ensuring pharmaceutical quality" – a set of FDA-enforced regulations that "provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities." *See* Food and Drug Administration, Facts About the Current Good Manufacturing Practices (CGMPs) *available at* https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practices-cgmps.

April 2015; (iii) whether manufacturing capacity was already being used to manufacture other drugs "such that it could not readily have been converted to [Exforge] at that time"; and (iv) whether Mylan's generic Exforge would have been prioritized over those other drugs.[39] Again, because Mylan has already identified the relevant custodians and departments who possess the requested categories of information in similar litigation,[40] any burden on Mylan to do so in this case is mitigated.

Plaintiffs' Subpoena Request Nos. 3-5 are not unduly burdensome, and Mylan should be ordered to comply with them.

V. CONCLUSION

The documents sought by Plaintiffs are relevant, appropriately limited in scope, and not unduly burdensome for Mylan to collect and produce. For the foregoing reasons, Plaintiffs respectfully request that this Court grant Plaintiffs' Motion to Compel and order Mylan to: (a) produce documents responsive to Plaintiffs' subpoena Requests Nos. 3, 4(i), 4(iii), 4(iv), 4(v), 4(vi), 4(vii), and 5 as narrowed in Plaintiffs' April 1, 2019 letter to Mylan (Ex. 5) and explained on pages 6-7, *supra*; and (b) immediately produce the documents Mylan has already agreed to produce in response to Requests Nos. 1, 2, 3, 4(i), 4(ii), 4(vii), 5, 7, 8, 9, and 15, as set forth in Exs. 5 and 6 and explained on page 5, *supra*.

[39] *See Namenda I*, 331 F. Supp. 3d at 171.

[40] *See, e.g.*, *supra* at 11-12 (discussing Mylan's production of a broader set of documents in the *Doryx* case, including "logistics and planning for launching products"); *see also* Ex. 8 at 3.

Dated: May 17, 2019

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 17, 2019, I, Dan Litvin, served the above Memorandum of Law via ECF on all counsel of record and via email on third party Mylan, Inc.

Dated: May 17, 2019

Respectfully Submitted,

/s/ Dan Litvin

Dan Litvin